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510(k) Summary

K033491

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

1) Submitter name, address, contact

Roche Diagnostics Corporation
9115 Hague Rd.
Indianapolis, IN 46250

Contact Person: Jennifer Tribbett

Date Prepared: August 11, 2004

2) Device name

Proprietary name: Cardiac D-Dimer Assay
Common name: D-Dimer
Classification name: Fibrinogen/Fibrin Degradation Product Assay

3) Predicate device

The Roche Diagnostics Cardiac D-Dimer Assay is substantially equivalent to other devices legally marketed in the United States. We claim equivalence to the Roche Diagnostics Tina-quant® D-Dimer Test System (K002706).

4) Device Description

The Cardiac D-Dimer Assay is intended for the quantitative determination of d-dimer in anticoagulated venous whole blood with the Cardiac Reader Instrument.

The test is based on the dual monoclonal antibody "sandwich" principle using a poly-(streptavidin)-biotin capture system with a gold sol particle label. The test is initiated by the addition of whole blood to the Cardiac D-Dimer Assay, which separates red blood cells from plasma. D-Dimer in plasma combines with both biotinylated anti-d-dimer antibody conjugated to gold sol particles, to form a "sandwich". This "sandwich" combines with poly-(streptavidin), which is immobilized in a stripe or line across the read window of the Cardiac D-Dimer Assay, producing a reddish purple line. The intensity and speed at which the color forms are related to the concentration of d-dimer in the blood.

5) Intended use

The Cardiac D-Dimer Assay is intended for the quantitative determination of d-dimer in anticoagulated venous whole blood with the Cardiac Reader Instrument.

6) Substantial equivalence – Similarities and Differences

The following tables show the comparison of the Cardiac D-Dimer Assay to the Tina-quant® D-Dimer Test System.

Topic	Tina-quant® D-Dimer Test System (K002706)	Cardiac D-Dimer Assay
Intended Use	Quantitative determination D-dimer in citrated plasma or heparin plasma.	Quantitative determination of d-dimer in anticoagulated venous whole blood.
Test Principle	Latex particles of uniform size are coated with monoclonal antibodies to the D-Dimer epitope. The antigen/antibody complexes produced by the addition of samples containing D-Dimer lead to an increase in the turbidity of the test reactants. The change in absorbance with time is dependent on the concentration of D-Dimer epitopes in the sample.	The test is based on the dual monoclonal antibody "sandwich" principle using a poly-(streptavidin)-biotin capture system with a gold sol particle label. The test is initiated by the addition of whole blood to the Cardiac D-Dimer Assay, which separates red blood cells from plasma. D-Dimer in plasma combines with both biotinylated anti-d-dimer antibody conjugated to gold sol particles, to form a "sandwich". This "sandwich" combines with poly-(streptavidin), which is immobilized in a stripe or line across the read window of the Cardiac D-Dimer Assay, producing a reddish purple line. The intensity and speed at which the color forms are related to the concentration of d-dimer in the blood.

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Topic	Tina-quant® D-Dimer Test System (K002706)	Cardiac D-Dimer Assay
Reagents	•Buffer •Anti-D-Dimer latex suspension of consisting of latex particles coated with monoclonal anti-human D-Dimer antibodies (mouse)	•Buffer •Biotinylated anti-d-dimer antibody (mouse monoclonal) •Gold-labeled anti-d-dimer antibody (mouse monoclonal)
Measuring Range	0.15 - 9.0 ug/ml	0.1 ug/ml - 4 ug/ml
Result Display	Quantitative	Semi-Quantitative **D-Dimer concentration** — **Display Format** Less than 0.1 ug/ml — "D-Dimer Low" Between 0.1 and 4 ug/ml — Displays quantitative result Greater than 4 ug/ml — "D-Dimer High > 4 ug/ml"

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Jennifer Tribbett
Regulatory Affairs Principal
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, Indiana 46250-0457

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Re: k033491
Trade/Device Name: Cardiac D-Dimer Assay
Regulation Number: 21 CFR § 864.7320
Regulation Name: Fibrin Degradation Products
Regulatory Class: II
Product Code: DAP, GHH
Dated: August 11, 2004
Received: August 12, 2004

Dear Ms. Tribbett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Robert L. Becker, Jr., M.D., Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K033491

Device Name: The CARDIAC D-Dimer Assay

Indications For Use:

The CARDIAC D-Dimer Assay is intended for the quantitative determination of d-dimer in anticoagulated venous whole blood with the CARDIAC Reader instrument.

D-Dimer is a degradation product of crosslinked firbrin. The d-dimer concentration is a measure of the fibrinolytic activity of plasmin in the vascular system. Elevated concentrations of d-dimer indicate increased coagulatory and fibrinolytic activity. In general, a validated d-dimer assay may be useful in ruling out deep venous thrombosis or pulmonary embolism.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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